§170.315(b)(9) Care plan

2015 Edition Cures Update CCG

Version 1.0 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	06-15-2020

Regulation Text

Regulation Text

§ 170.315 (b)(9) *Care plan—*

Enable a user to record, change, access, create, and receive care plan information in accordance with:

(i) The Care Plan document template, including the Health Status Evaluations and Outcomes Section and Interventions Section (V2), in the standard specified in § 170.205(a)(4); and

(ii) The standard in § 170.205(a)(5)) on and after May 2, 2022.

Standard(s) Referenced

Applies to entire criterion

§ 170.205(a)(4) Health Level 7 (HL7®) Implementation Guide for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5)

Certification Companion Guide: Care plan

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the *21st Century Cures Act:*

Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule). It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the ONC Cures Act Final Rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
New	No	Not Included	No

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(b)(9). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(b) "paragraph (b)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (a) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))

- Emergency access (§ 170.315(d)(6))
- End-user device encryption (§ 170.315(d)(7))
- Integrity (§ 170.315(d)(8))
- Encrypt authentication credentials (§ 170.315(d)(12))
- Multi-factor authentication (MFA) (§ 170.315(d)(13))

- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for Approach 1, the health IT developer may certify using system documentation that is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces for each applicable P&S certification criterion that enable the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied Consolidated-Clinical Document Architecture (C-CDA) creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance Certification Companion Guide for more details.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

- Consolidated CDA creation performance (§ 170.315(g)(6))

Technical Explanations and Clarifications

Applies to entire criterion

Technical outcome – A user can record, change, access, create, and receive care plan information according to the Care Plan document template in the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, including the Health Status Evaluations and Outcomes Section and Interventions Section (V2).

Clarifications:

- In combination with the C-CDA R2.1 standard, developers certifying to the Care Plan criterion must follow the guidance and templates provided in HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2 for implementation of the C-CDA Release 2.1 standard.
- The Care Plan document template supports broader information about the patient, including education, physical therapy/range of motion, and social interventions not commonly found in other parts of the C-CDA standard and is also distinct from the 'Plan of Treatment Section' in Version 2.1 of the C-CDA. (The Plan of Care Section in C-CDA 1.1 was renamed Plan of Treatment Section in C-CDA 2.1). [see also 80 FR 62648]
- The Care Plan document template is distinct from the “Plan of Care Section” in previous versions of the C-CDA. [see also 80 FR 62648]
- Consistent with ONC policy, health IT must enable a user to record, change, access, create, and receive information for those sections of the C-CDA Care Plan template that are required, including the “Goals” and “Health Concerns” Sections. [see also 80 FR 62648] We would expect that these sections could contain patient-expressed information, including patient-expressed goals and health concerns. Because of this, the information contained within the “Goals” and “Health Concerns” Sections of the care plan document could differ from the information contained within those same sections in a transition of care/referral summary document.
- Health IT must enable a user to record, change, access, create, and receive information for the “Health Status Evaluations and Outcomes Section” and “Interventions Section (V2)”. Although these sections are deemed optional in the C-CDA standard, they are required for certification. [see also 80 FR 62649]

- Although a system will need to be able to receive a care plan in accordance with C-CDA Release 2.1, the system is not required to enable a user to reconcile the care plan data. [see also 80 FR 62649]
- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see Frequently Asked Questions #51] Certified health IT adoption and compliance with the following corrections are necessary because they implement updates to vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA documents. There is a 90-day delay from the time the CCG has been updated with the ONC-approved corrections to when compliance with the corrections will be required to pass testing (i.e., ETT: Message Validators – Cures Update C-CDA R2.1 Validator). Similarly, there will be an 18-month delay before a finding of a correction's absence in certified health IT during surveillance would constitute a non-conformity under the Program.

Content last reviewed on June 22, 2020